REMARKS

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the herein remarks and accompanying information, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

The amendment to the specification corrects the terms that describe the polypeptides presented in Table 1, such that it is now in accordance with the text of paragraph 0024.

No new matter is added.

Claims 1-15 are currently under consideration. Claims 1, 7, 12, and 14 are amended and claims 6, 8-11, 13, and 15 are cancelled without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that the claims herewith are patentably distinct over the prior art, and these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments to the claims presented herein are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply to clarify the scope of protection to which Applicant is entitled. Support for amended claims 1, 7, 12, and 14 can be found, for example, in paragraphs 0010 and 0012-0015, and in Example 2 of the specification.

II. REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, ARE OVERCOME

The rejection of claims 1-15 under 35 U.S.C. § 112, first paragraph was maintained as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. The rejection is respectfully traversed.

According to the Court of Appeals for the Federal Circuit in the case of *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988),

> Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. 'The key word is undue, not experimentation.' The determination of what constitutes undue

> experimentation in a given case requires the application of standard of reasonableness, having due regard for the nature of the invention and the state of the art. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed ... [Citations omitted]. *Id.* at 1404.

Determining whether undue experimentation is required to practice a claimed invention turns on weighing many factors summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988), for example: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples of the invention; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims.

Thus, it is respectfully submitted that for a proper Section 112, first paragraph, lack of enablement analysis, an Office Action must show that the *Wands* factors are not met. Simply, it is respectfully asserted that the lack of enablement rejection fails to provide a fact based analysis using the *Wands* factors that supports the proposition the claimed invention require **undue** experimentation.

The Examiner is respectfully reminded that a specification need not contain any example of the invention, as the issue is whether the disclosure enables one skilled in the art to practice the invention without undue experimentation. *In re Borkowski*, 422 F.2d 904, 164 USPQ 642 (CCPA 1970). Simply, a determination that undue experimentation is necessary to practice the invention does not necessarily follow from a lack of examples in the specification. And, the Examiner is further respectfully reminded that an applicant need not describe all actual embodiments of a claimed invention.

The Office Action alleges that the compounds demonstrated to treat hyperlipidemia in the specification have a different structure than the compounds disclosed in the claims, and that minor changes in structure often eliminate activity. The Office Action contends that the absence of working examples and unpredictability in the art would require a skilled artisan to undue experimentation in order to practice the invention.

In response, Applicant has clarified claims 1 and 7 to indicate that the peptide can be modified such that the C-terminal COOH group of the peptide is amidated, the NH group is

replaced with a COOH group in the case of D-Pro DTyr D Val,, or the NH_2 group is replaced with a COOH group for D-Leu D-Thr D-Va. The compounds disclosed in amended claims 1 and 7 are discussed in the specification, namely in Table 2, which presents peptides with a C-terminal having a carboxamide form, and paragraphs 0010 and 0012-15. Further, Examples 1 and 2 clearly describe the synthesis of the compounds and the affects of the compounds after oral administration. Thus, the working examples of the present application would enable one skilled in the art to make and use the claimed invention.

In addition, the Office Action indicates that the scope of the previously presented claims did not encompass the compounds exemplified in the specification because, for example, the presence of the C-terminal amidation. The amendment to claims 1 and 7 effectively revises the scope and breadth of the invention, such that the compounds provided in the Examples are encompassed by the claims of the invention. Also, the basis of the allegation that undue experimentation is required due to unpredictability in the art is rendered moot. Therefore, the Office Action does not provide evidence that the instant invention would require undue experimentation due to the unpredictability in art or the breadth of the claims.

Accordingly, reconsideration and withdrawal of the rejection of claims 1-15 under 35 U.S.C. §112, first paragraph, are respectfully requested.

III. REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH, ARE OVERCOME

Claims 1-15 are rejected under 35 U.S.C. § 112, second paragraph as containing being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The rejection is respectfully traversed.

Specifically, the Office Action alleges that claims 1 and 7 are not drawn to a pharmaceutical composition because a "composition" contains at least two compounds and claim 1 only describes one compound. In response, Applicant has amended claims 1 and 7 to clarify that the pharmaceutical composition also contains a pharmaceutically acceptable carrier.

The Office Action also contends that claim 1 unnecessarily recites the phrase "for administration to a human or animal," as a pharmaceutical composition can only be administered to a human or animal. As a result, Applicant has removed the phrase from claim 1.

Furthermore, according to the Office Action, the term "component" in claims 1, 7, 12, and 14 should be replaced by the term "compound." Applicant respectfully notes that amended claims 1, 7, 12, and 14 presented herein do not contain the term "component." The amendment to the claims, therefore, obviates this rejection.

Finally, the Office Action asserts that claims 8-11, 13 and 15 are not subgeneric to claim 1, because claim 1, as previously presented, excludes the possibility that the C-terminal carboxyl group and the N-terminal amino group can be replaced. In response, Applicants have cancelled claims 8-11, 13 and 15, thereby obviating this rejection.

Accordingly, reconsideration and withdrawal of the rejection of claims 1-15 under 35 U.S.C. § 112, second paragraph are respectfully requested.

IV. REJECTION UNDER 35 U.S.C. § 103 IS OVERCOME

Claim 1 is rejected under 35 U.S.C. § 103 as being unpatentable over Baumbach et al. (U.S. Patent No. 5,831,003; hereinafter "Baumbach"), Nestor et al. (U.S. Patent No. 4,473,555; hereinafter "Nestor"), or Seelig (U.S. Patent No. 5,451,658). The rejection is respectfully traversed.

According to the Office Action, Baumbach, Nestor, and Seelig each allegedly disclose peptides that contain the tripeptide Pro-Tyr-Val as a subsequence. The Office Action contends that while the tripeptide of the references are "L" amino acids and the tripeptide of claim 1 is all "D" amino acids, it is well known in the art to switch "L" amino acids with "D" amino acids.

In response, Applicant respectfully argues that the amended claims presented herein do not recite a larger peptide sequence wherein D-Pro D-Tyr D-Val and D-Leu D-Thr D-Val serve as mere subsequences. On the contrary, the amended claims disclose a "stand alone" peptide, as indicated by the phrase "the peptide is selected from the group...," and the removal of the phrase "as an active component." Section 2143 of the MPEP indicates that the cited references must teach or suggest all of the claim limitations, and Baumbach, Nestor, and Seelig do not teach or even suggest the stand-alone peptide disclosed in the present invention. Therefore, the present invention is not obvious in view of these references.

Further, the Office Action admits that the amino acids of the cited references are of the "L" form and not the "D" form as disclosed in the present invention. The Office Action further alleges that it is well known in the art to switch "L" amino acids with "D" amino acids, and that

one would be motivated to change forms to increase resistance to protease digestion. Applicant respectfully notes that it is also well known that switching the forms of the amino acids creates entirely different chemical entities. A skilled artisan would not be motivated to change the amino acids of the cited references to "D" amino acids, because there would be no indication that the amino acids in the "D" form would be capable of biological activity **and** proteolytic resistance. Applicants argue that developing "D" amino acids peptides to demonstrate both biological activity **and** proteolytic resistance is not a trivial matter; that the present invention discloses **retro inverso** peptides rather than merely **retro** peptides supports this argument. Section 2143 of the MPEP states that, in order to establish a case of obviousness, there must be a reasonable expectation of success. As such, a skilled artisan would not reasonably expect that switching "L" amino acids to "D" amino acids would successfully result in a peptide capable of both biological activity and proteolytic resistance.

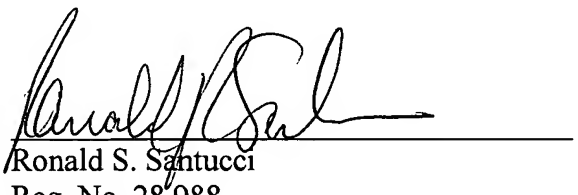
Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 103 are respectfully requested.

CONCLUSION

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP

By: 

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